EYE ALLERGY ITCH AND REDNESS RELIEF TWICE DAILY RELIEF- olopatadine hydrochloride ophthalmic solution/ drops

Dr. Reddy's Laboratories Inc.

ACTIVE INGREDIENT

Olopatadine (0.1%) (equivalent to olopatadine hydrochloride 0.111%)

PURPOSE

Antihistamine and redness reliever

USES

temporarily relieves itchy and red eyes due to pollen, ragweed, grass, animal hair and dander

WARNINGS

For external use only

DO NOT USE

- if solution changes color or becomes cloudy
- if you are sensitive to any ingredient in this product
- to treat contact lens related irritation

WHEN USING THIS PRODUCT

- do not touch tip of container to any surface to avoid contamination
- remove contact lenses before use
- wait at least 10 minutes before reinserting contact lenses after use
- do not wear a contact lens if your eye is red

STOP USE AND ASK DOCTOR IF

you experience:

- eye pain
- changes in vision
- increased redness of the eye
- itching worsens or lasts for more than 72 hours

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

adults and children 2 years of age and older:

- put 1 drop in the affected eye(s) twice daily, every 6 to 8 hours, no more than twice per day
- if using other ophthalmic products while using this product, wait at least 5 minutes between each product
- replace cap after each use
- children under 2 years of age: consult a doctor

OTHER INFORMATION

- only for use in the eye
- store between 4° to 25°C (39° to 77°F)

INACTIVE INGREDIENTS

Benzalkonium chloride 0.01%, Dibasic sodium phosphate, Hydrochloric acid and /or Sodium hydroxide (to adjust pH), Sodium chloride and Water for Injection.

QUESTIONS?

Call 1-888-375-3784

PRINCIPAL DISPLAY PANEL

Carton Label



EYE ALLERGY ITCH AND REDNESS RELIEF TWICE DAILY RELIEF

olopatadine hydrochloride ophthalmic solution/ drops

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:43598-826(NDC:43598-765) Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (OLOPATADINE - UNII:D27V6190PM)	OLOPATADINE	1 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7)				
SODIUM PHO SPHATE, DIBASIC (UNII: GR686LBA74)				
HYDRO CHLORIC ACID (UNII: QTT17582CB)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:43598-826- 07	1 in 1 CARTON	09/01/2020			
1	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
ANDA	ANDA209619	09/01/2020			

Labeler - Dr. Reddy's Laboratories Inc. (802315887)

Revised: 8/2020 Dr. Reddy's Laboratories Inc.